



RULE-MAKING ORDER

CR-103P (May 2009)
(Implements RCW 34.05.360)

Agency: Office of the Insurance Commissioner

Permanent Rule Only

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes

☒ No

If Yes, explain:

Purpose: Explain the standards applied by the Commissioner when reviewing a plan's coverage standards for its prescription drug benefit, and requiring specific disclosures to enrollees about how to request substitution of formulary medications and about formulary changes.

Insurance Commissioner Matter No. R 2012-03

Citation of existing rules affected by this order:

Repealed: 0

Amended: 0

Suspended: 0

Statutory authority for adoption: RCWs 48.02.060;48.02.062; 48.18.140; 48.43.525; 48.44.050;48.44.440(2); 48.44.460(2); 48.46.200; 48.46.510.

Other authority :

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 12-14-116 on July 5, 2012.

Describe any changes other than editing from proposed to adopted version:

WAC 284-43-816 does not include a reference to the formulary in the initial paragraph. It also includes a new (3), clarifying the generic first standard set forth in the section by noting that patient tolerance or response to medication is a specific basis that may require access to a non-formulary medication. The (3) in the proposed rule is not (4) in the final rule. WAC 284-43-817 (1) was changed based on comments, to encompass all types of alternative products, not just generic products.

WAC 284-43-817(5) was added, at the request of carriers, to confirm the fact that the substitution process itself is not a grievance or appeal process.

WAC 284-43-819(2) no longer contains the phrase "and must not contribute to the carrier's underwriting gain for the plan" in the last sentence. WAC 284-43-819(3) now clarifies that carriers may include underwriting gain in their product pricing, but that substitution based on this section may not result in additional gain beyond the original pricing.

WAC 284-43-825(1)(b) was edited for clarity regarding the expectation for notice, and establishes a specific, more limited class of enrollees to whom the carrier must provide notice of a formulary change.

WAC 284-43-850 now contains language identical to that in the Affordable Care Act. The language provides clarity about the applicability of network requirements, and the list of services or items for which coverage may be denied. The definition of life-threatening condition from the Affordable Care Act is included.

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Date adopted: October 4, 2012

CODE REVISER USE ONLY

NAME (TYPE OR PRINT)

Mike Kreidler

SIGNATURE

TITLE

Insurance Commissioner

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: October 08, 2012

TIME: 10:54 AM

WSR 12-21-019

(COMPLETE REVERSE SIDE)

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	_____	Amended	_____	Repealed	_____
Federal rules or standards:	New	_____	Amended	_____	Repealed	_____
Recently enacted state statutes:	New	_____	Amended	_____	Repealed	_____

The number of sections adopted at the request of a nongovernmental entity:

New	<u>1</u>	Amended	_____	Repealed	_____
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The number of sections adopted in the agency's own initiative:

New	<u>6</u>	Amended	_____	Repealed	_____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>7</u>	Amended	_____	Repealed	_____
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The number of sections adopted using:

Negotiated rule making:	New	_____	Amended	_____	Repealed	_____
Pilot rule making:	New	_____	Amended	_____	Repealed	_____
Other alternative rule making:	New	<u>7</u>	Amended	_____	Repealed	_____

NEW SECTION

WAC 284-43-816 General prescription drug benefit requirements. A health carrier must not offer, renew, or issue a health benefit plan providing a prescription drug benefit, which the commissioner determines results or can reasonably be expected to result in an unreasonable restriction on the treatment of patients. A carrier may restrict prescription drug coverage based on contract or plan terms and conditions that otherwise limit coverage, such as a preexisting condition waiting period, or medical necessity.

(1) A carrier must ensure that a prescription drug benefit covers Federal Drug Administration approved prescribed drugs, medications or drug therapies that are the sole prescription drug available for a covered medical condition.

(2) A prescription drug benefit that only covers generic drugs constitutes an unreasonable restriction on the treatment of patients.

(3) A prescription drug benefit or formulary must not exclude coverage for a nonformulary drug or medication if the only formulary drug available for an enrollee's covered condition is one that the enrollee cannot tolerate or that is not clinically efficacious for the enrollee.

(4) Nothing in this chapter is intended to limit or deter the use of "Dispense as Written" prescriptions, subject to the terms and conditions of the health plan.

NEW SECTION

WAC 284-43-817 Prescription drug benefit design. (1) A carrier may design its prescription drug benefit to include cost control measures, including requiring preferred drug substitution in a given therapeutic class, if the restriction is for a less expensive, equally therapeutic alternative product available to treat the condition.

(2) A carrier may include elements in its prescription drug benefit design that, where clinically feasible, create incentives for the use of generic drugs. Examples of permitted incentives include, but are not limited to, refusal to pay for higher cost drugs until it can be shown that a lower cost drug or medication is not effective (also known as step therapy protocols or fail-first policies), establishing a preferred brand and nonpreferred brand formulary, or otherwise limiting the benefit to the use of a

generic drug in lieu of brand name drugs, subject to a substitution process as set forth in subsection (3) of this section.

(3) A carrier must establish a process that a provider and enrollee may use to request a substitution for a covered prescribed therapy, drug or medication.

(a) The process must not unreasonably restrict an enrollee's access to nonformulary or alternate medications for refractory conditions. Used in this context, "refractory" means "not responsive to treatment."

(b) A carrier's substitution process must not result in delay in treating an enrollee's emergency fill or urgent care needs, or expedited requests for authorization. Subject to the terms and conditions of the policy that otherwise limit or exclude coverage, the carrier must permit substitution of a covered generic drug or formulary drug if:

(i) An enrollee does not tolerate the covered generic or formulary drug; or

(ii) An enrollee's provider determines that the covered generic or formulary drug is not therapeutically efficacious for an enrollee. A carrier may require the provider to submit specific clinical documentation as part of the substitution request; or

(iii) The provider determines that a dosage is required for clinically efficacious treatment that differs from a carrier's formulary dosage limitation for the covered drug. A carrier may require the provider to submit specific clinical documentation as part of the substitution request and must review that documentation prior to making a decision.

(4) A carrier may include a preauthorization requirement for its prescription drug benefit and its substitution process, based on accepted peer reviewed clinical studies, Federal Drug Administration black box warnings, the fact that the drug is available over-the-counter, objective and relevant clinical information about the enrollee's condition, specific medical necessity criteria, patient safety, or other criteria that meet an accepted, medically applicable standard of care.

(a) Neither the substitution process criteria nor the type or volume of documentation required to support a substitution request may be unreasonably burdensome to the enrollee or their provider.

(b) The substitution process must be administered consistently, and include a documented consultation with the prescribing provider prior to denial of a substitution request.

(5) Use of a carrier's substitution process is not a grievance or appeal pursuant to RCW 48.43.530 and 48.43.535. Denial of a substitution request is an adverse benefit determination, and an enrollee, their representative provider or facility, or representative may request review of that decision using the carrier's appeal or adverse benefit determination review process.

NEW SECTION

WAC 284-43-818 Formulary changes. A carrier is not required to use a formulary as part of its prescription drug benefit design. If a formulary is used, a carrier must, at a minimum, comply with these requirements when a formulary change occurs.

(1) In addition to the requirements set forth in WAC 284-30-450, a carrier must not exclude or remove a medication from its formulary if the medication is the sole prescription medication option available to treat a disease or condition for which the health benefit plan, policy or agreement otherwise provides coverage, unless the medication or drug is removed because the drug or medication becomes available over-the-counter, is proven to be medically inefficacious, or for documented medical risk to patient health.

(2) If a drug is removed from a carrier's formulary for a reason other than withdrawal of the drug from the market, availability of the drug over-the-counter, or the issue of black box warnings by the Federal Drug Administration, a carrier must continue to cover a drug that is removed from the carrier's formulary for the time period required for an enrollee who is taking the medication at the time of the formulary change to use a carrier's substitution process to request continuation of coverage for the removed medication, and receive a decision through that process, unless patient safety requires swifter replacement.

(3) Formularies posted on a carrier or a carrier's contracted pharmacy benefit manager web site must be current. Unless the removal is done on an immediate or emergency basis or because a generic equivalent becomes available without prior notice, formulary changes must be posted thirty days before the effective date of the change. In the case of an emergency removal, the change must be posted as soon as practicable, without unreasonable delay.

NEW SECTION

WAC 284-43-819 Cost-sharing for prescription drugs. (1) A carrier and health plan unreasonably restrict the treatment of patients if an ancillary charge, in addition to the plan's normal copayment or coinsurance requirements, is imposed for a drug that is covered because of one of the circumstances set forth in either WAC 284-43-817 or 284-43-818. An ancillary charge means any payment required by a carrier that is in addition to or excess of cost-sharing explained in the policy or contract form as approved by the commissioner. Cost-sharing means amounts paid directly to a provider or pharmacy by an enrollee for services received under the health benefit plan, and includes copayment, coinsurance, or deductible amounts.

(2) When an enrollee requests a brand name drug from the formulary in lieu of a therapeutically equivalent generic drug or a drug from a higher tier within a tiered formulary, and there is not a documented clinical basis for the substitution, a carrier may require the enrollee to pay for the difference in price between the drug that the formulary would have required, and the covered drug, in addition to the copayment. This charge must reflect the actual cost difference.

(3) When a carrier approves a substitution drug, whether or not the drug is in the carrier's formulary, the enrollee's cost-sharing for the substitution drug must be adjusted to reflect any discount agreements or other pricing adjustments for the drug that are available to a carrier. Any charge to the enrollee for a substitution drug must not increase the carrier's underwriting gain for the plan beyond the gain contribution calculated for the original formulary drug that is replaced by the substitution.

(4) If a carrier uses a tiered formulary in its prescription drug benefit design, and a substitute drug that is in the formulary is required based on one of the circumstances in either WAC 284-43-817 or 284-43-818, the enrollee's cost sharing may be based on the tier in which the carrier has placed the substitute drug.

NEW SECTION

WAC 284-43-825 Prescription drug benefit disclosures. (1) A carrier must include the following information in the certificate of coverage issued for a health benefit plan, policy or agreement that includes a prescription drug benefit:

(a) A clear statement explaining that the health benefit plan, policy or agreement may cover brand name drugs or medication under the circumstances set forth in WAC 284-43-817 or 284-43-818, including, if a formulary is part of the benefit design, brand name drugs or other medication not in the formulary.

(b) A clear explanation of the substitution process that the enrollee or their provider must use to seek coverage of a prescription drug or medication that is not in the formulary or is not the carrier's preferred drug or medication for the covered medical condition.

(2) When a carrier eliminates a previously covered drug from its formulary, or establishes new limitations on coverage of the drug or medication, at a minimum a carrier must ensure that prior notice of the change will be provided as soon as is practicable, to enrollees who filled a prescription for the drug within the prior three months.

(a) Provided the enrollee agrees to receive electronic notice and such agreement has not been withdrawn, either electronic mail notice, or written notice by first class mail at the last known address of the enrollee, are acceptable methods of notice.

(b) If neither of these notice methods is available because

the carrier lacks contact information for enrollees, a carrier may post notice on its web site or at another location that may be appropriate, so long as the posting is done in a manner that is reasonably calculated to reach and be noticed by affected enrollees.

(3) A carrier and health plan may use provider and enrollee education to promote the use of therapeutically equivalent generic drugs. The materials must not mislead an enrollee about the difference between biosimilar or bioequivalent, and therapeutically equivalent, generic medications.

NEW SECTION

WAC 284-43-840 Anticancer medication. A carrier and health plan must cover prescribed, self-administered anticancer medication that is used to kill or slow the growth of cancerous cells on at least a comparable basis to the plan's coverage for the delivery of cancer chemotherapy medications administered in a clinical or medical setting.

(1) A carrier may not impose dollar limits, copayments, deductibles or coinsurance requirements on coverage for orally administered anticancer drugs or chemotherapy that are less favorable to an insured or enrollee than the dollar limits, copayments, deductibles or coinsurance requirements that apply to coverage for anticancer medication or chemotherapy that is administered intravenously or by injection.

(2) A carrier may not reclassify an anticancer medication or increase an enrollee's out-of-pocket costs as a method of compliance with the requirements of this section.

NEW SECTION

WAC 284-43-850 Clinical trials. A carrier must not restrict coverage of routine patient costs for enrollees who participate in a clinical trial. "Routine costs" means items and services delivered to the enrollee that are consistent with and typically covered by the plan or coverage for an enrollee who is not enrolled in a clinical trial. A carrier may continue to apply its limitations and requirements related to use of network services.

(1) A carrier may require enrollees to meet the eligibility requirements of the clinical trial according to the trial protocol. While not required to impose such a condition, a carrier may refuse coverage under this section if the enrollee does not provide medical and scientific information establishing that the

individual's participation in such trial would be appropriate based on the individual meeting the eligibility requirements for the clinical trial, unless the enrollee is referred to the clinical trial by a health care provider participating in the carrier's network.

(2) This includes the cost of prescription medication used for the direct clinical management of the enrollee, unless the trial is for the investigation of the prescription medication or the medication is typically provided by the research sponsors free of charge for any enrollee in the trial.

(3) The requirement does not apply to:

(a) A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis;

(b) For items and services provided solely to satisfy data collection and analysis needs;

(c) Items and services that are not used in the direct clinical management of the enrollee; or

(d) The investigational item, device, or service itself.

(4) Clinical trial means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition, funded or approved by:

(a) One of the National Institutes of Health (NIH);

(b) An NIH cooperative group or center which is a formal network of facilities that collaborate on research projects and have an established NIH-approved peer review program operating within the group including, but not limited to, the NCI Clinical Cooperative Group and the NCI Community Clinical Oncology Program;

(c) The federal Departments of Veterans Affairs or Defense;

(d) An institutional review board of an institution in this state that has a multiple project assurance contract approval by the Office of Protection for the Research Risks of the NIH; and

(e) A qualified research entity that meets the criteria for NIH Center Support Grant eligibility.

"Life threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.